

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61B 5/03, A63B 23/20	A1	(11) International Publication Number: WO 97/10746
		(43) International Publication Date: 27 March 1997 (27.03.97)

(21) International Application Number: PCT/GB96/02296
(22) International Filing Date: 20 September 1996 (20.09.96)

(30) Priority Data:
9519194.6 20 September 1995 (20.09.95) GB

(71) Applicant (for all designated States except US): UNIVERSITY OF WALES COLLEGE OF MEDICINE [GB/GB]; Heath Park, Cardiff CF4 4XN (GB).

(72) Inventors; and

(75) Inventors/Applicants (for US only): YOUNG, Howard, Leslie [GB/GB]; 56 Cheriton Drive, Thornhill, Cardiff CF4 5DF (GB). LOWNDES, Richard, Herbert [GB/GB]; Pelvic Floor and G.I. Physiology Unit, West Norwich Hospital, Bowthorpe Road, Norwich NR2 3TU (GB).

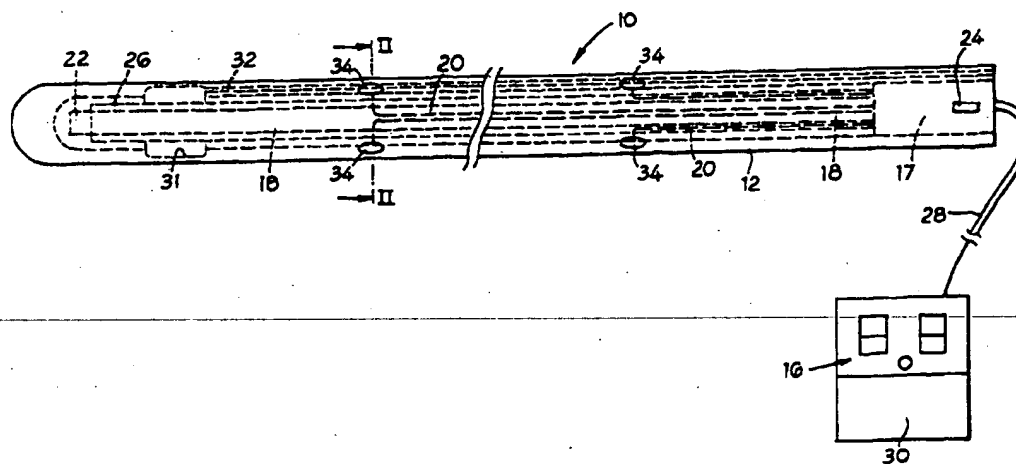
(74) Agents: NEWELL, William, Joseph; Wynne-Jones, Laine & James, 22 Rodney Road, Cheltenham, Gloucestershire GL50 1JJ (GB) et al.

(81) Designated States: AU, CA, GB, JP, US, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published

With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: ANORECTAL ANGLE MEASUREMENT



(57) Abstract

Apparatus (10) for measuring the anorectal angle comprises an outer rubber-like sheath (12), which may be a suitably modified catheter, within which is disposed an elongate angular deflection detector (14) which provides on display (16) a read-out of the angular deflection of the apparatus. The sheath (12) may include pressure ports with associated pressure lines back to the proximal end of the sheath to allow the pressure to be read at different points along the anal canal.

BEST AVAILABLE COPY

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AM	Armenia	GB	United Kingdom	MW	Malawi
AT	Austria	GE	Georgia	MX	Mexico
AU	Australia	GN	Guinea	NE	Niger
BB	Barbados	GR	Greece	NL	Netherlands
BE	Belgium	HU	Hungary	NO	Norway
BF	Burkina Faso	IE	Ireland	NZ	New Zealand
BG	Bulgaria	IT	Italy	PL	Poland
BJ	Benin	JP	Japan	PT	Portugal
BR	Brazil	KE	Kenya	RO	Romania
BY	Belarus	KG	Kyrgyzstan	RU	Russian Federation
CA	Canada	KP	Democratic People's Republic of Korea	SD	Sudan
CF	Central African Republic	KR	Republic of Korea	SE	Sweden
CG	Congo	KZ	Kazakhstan	SG	Singapore
CH	Switzerland	LI	Liechtenstein	SI	Slovenia
CI	Côte d'Ivoire	LK	Sri Lanka	SK	Slovakia
CM	Cameroon	LR	Liberia	SN	Senegal
CN	China	LT	Lithuania	SZ	Swaziland
CS	Czechoslovakia	LU	Luxembourg	TD	Chad
CZ	Czech Republic	LV	Latvia	TG	Togo
DE	Germany	MC	Monaco	TJ	Tajikistan
DK	Denmark	MD	Republic of Moldova	TT	Trinidad and Tobago
EE	Estonia	MG	Madagascar	UA	Ukraine
ES	Spain	ML	Mali	UG	Uganda
FI	Finland	MN	Mongolia	US	United States of America
FR	France	MR	Mauritania	UZ	Uzbekistan
GA	Gabon			VN	Viet Nam

ANORECTAL ANGLE MEASUREMENT

This invention relates to apparatus and methods for measuring the anorectal angle and more generally to apparatus and methods for measuring, monitoring or observing
5 the local anatomy or selected parameters in the anal canal and/or rectum.

Measurement of the anorectal angle (the angle of the anus relative to the rectum) is part of the investigations undertaken to determine the functionality of the anal canal
10 and rectum in patients suffering defecatory disorders. The passage of stools is controlled by a muscular sling which controls the anorectal angle, between an acute angle (closed) and an obtuse angle (open). Lack of proper control can lead to constipation or faecal incontinence. In
15 addition to anorectal angle, the manometric pressure at various points in the rectum and anal canal may be detected, and electro-myological readings may be taken to determine muscle activity.

Generally, the measurement of the anorectal angle has
20 been performed by inserting into the rectum of the patient a radiological contrast medium which has the consistency of a soft stool, to simulate a soft faecal motion. The patient then sits on a radiolucent toilet and is screened radiologically whilst defecating. The difference between
25 the angle of the rectum before and during defecation provides some indication as to whether there may be a functional disorder of the anorectum in patients who have

problems in defecating. This procedure is referred to as a defecating proctogram and is unpleasant for the patient, invasive (requiring exposure to radiation) and many Radiological Units will not or cannot perform the procedure.

5 The procedure also of course requires special equipment and a skilled radiologist to observe and interpret the results.

A need therefore exists for an apparatus and method for use in monitoring the anal canal and/or rectum, for example for measuring anorectal angle which, alleviates at least

10 some of the above problems, allowing the measurement to be carried out more widely.

Accordingly, in one aspect, this invention provides a method for use in monitoring the anal canal and/or rectum of a patient, which comprises inserting through the anus into

15 the rectum an elongate flexible element and measuring or observing the angular deflection of said flexible element, and/or the contour adopted thereby.

Preferably, said angular deflection is measured in a single plane, for example the horizontal plane if the

20 patient is lying on his or her side.

Preferably the change of said angular deflection is measured during a simulated defecatory process.

Preferably, said angular deflection is measured using a sensor associated with said elongate flexible element.

25 Thus in preferred embodiments of this invention, the anorectal angle may be measured without requiring exposure to radiation and without requiring the patient to defecate.

In another aspect, this invention provides apparatus

for use in monitoring the anal canal and/or rectum of a patient, which apparatus comprises an elongate flexible element designed to be introduced via the anus into the rectum and having associated therewith angular deflection
5 detecting means for detecting the angular deflection thereof and/or the contour adopted by said flexible element.

Preferably, said angular deflection detecting means comprises an elongate flexible core element and sensor means responsive to longitudinal strain disposed along opposed
10 sides of the core element to determine angular deflection between spaced regions thereof. In one embodiment, the sensor means comprise respective elongate strain gauges extending along substantially the whole length of the elongate flexible core element at circumferentially spaced
15 locations.

Preferably said elongate flexible element comprises a rubber or rubber-like outer sheath within which is disposed said angular deflection detecting means.

Preferably, said outer sheath includes an inflatable
20 region in the distal position thereof, and whereby said region may be inflated in use to stimulate the rectum.

Preferably, said apparatus includes pressure detecting means for determining in use the pressure acting in the rectum or adjacent the anus. The pressure detecting means
25 may comprise one or more pressure sensors located in the outer sheath or pressure ports disposed in the outer sheath leading to one or more associated sensors.

In this way, a single instrument may be provided which

provides a reading of anorectal angle and manometric pressure, and so a 3-D pressure map of pressures within the anorectal region may be constructed.

In a further aspect, this invention provides use of the apparatus as defined as a bio-feedback sensor for training patients with defecatory disorders.

Whilst the invention has been described above, it extends to any inventive combination of features set out above or in the following description.

The invention may be performed in a various ways and an embodiment thereof will now be described in detail, reference being made to the accompanying drawings in which:-

Figure 1 is a schematic side view of apparatus in accordance with this invention;

Figure 2 is a cross sectional view on an enlarged scale of the apparatus of Figure 1, and

Figure 3 is a schematic view showing the apparatus in use.

The apparatus 10 for measuring anorectal angle comprises an outer rubber-like sheath 12, which may be a suitably modified catheter, within which is disposed an elongate angular deflection detector 14 which provides on display 16 a read-out of the angular deflection of the apparatus.

Referring to Figures 1 and 2, the angular deflection detector 14 comprises an anchorage or "fixed" end 17 from which extends a core element 18 of flexible wire or cable and four strain gauge wires 20 extending along the length of

the core and equispaced at 90° around the core, the whole being covered in thin plastics cover 21 (see Figure 2). Such a detector is obtainable from Penny and Giles Limited, Blackwood, Gwent, U.K.

5 The strains experienced by the strain gauge wires 20 are calculated to determine the total strain acting along the whole core on all four sides, thereby to determine the angular deflection between the tip 22 and the anchorage 17. In this particular example, only deflections in the plane of
10 the section shown in Figure 3 are monitored. The apparatus includes a mark 24 on the outer sheath to ensure that the instrument is used in the correct orientation. Also, as the accuracy of this particular sensor will be degraded if the angular deflection detector 14 is twisted, the apparatus
15 includes thin flexible strips 26 to either side of the detector to ensure that flexing of the apparatus is confined to the single plane only. From the anchorage 17 the signals are fed by a cable 28 to a processor 30 which drives the display 16. The output is also available to interface with
20 a suitable PC/software package (not shown) to allow the output from the instrument to sampled, correlated and/or combined with data from the other sensors for further processing as required.

25 The outer sheath 12 has a central bore in which the deflection detector 14 and strips 26 are snugly located, and the sheath 12 is bonded to the detector anchorage 17. The sheath induces an inflatable balloon chamber 31 at its distal end, fed by a line 32 which runs back to the proximal

end of the device. Likewise eight pressure sample points 34 are located along the extension of the sheath and respective passages run back to the distal end.

In use, the apparatus is inserted into the anus of a patient with the mark 24 aligned with the anterior plane of the patient and pushed in until the distal end is well into the patient's rectum, as seen in Figure 3. Measurements of angle and pressure may be taken. The balloon 31 may be inflated to stimulate defecation or the patient may be asked to push, and the corresponding change in angle measured.

The apparatus gives a quick read out which does not require interpretation to determine the actual angle, and so a numerical score can be given easily. There is minimal invasion of patient privacy compared to the defecating proctogram.

The apparatus is especially suited to bio-feedback, as a patient may be given the apparatus and instructed to practice regularly to obtain a particular angle on the display. In this way, the patient may relearn the appropriate response which may have been lost previously.

CLAIMS

1. A method for use in monitoring the anal canal and/or rectum of a patient, which method comprises inserting through the anus into the rectum an elongate flexible
5 element and measuring or observing the angular deflection of said flexible element and/or the contour adopted thereby.
2. A method according to Claim 1, wherein said angular deflection is measured in a single plane.
3. A method according to Claim 1 or Claim 2, wherein the
10 change of said angular deflection is measured during a simulated defacatory process.
4. A method according to any preceding Claim wherein said angular deflection is measured using a sensor associated with said elongate flexible element.
- 15 5. A method according to any preceding Claim, which further includes monitoring the pressure at one or more points in the anal canal and/or rectum using one or more sensor means provided on said elongate flexible element.
6. Apparatus for use in monitoring the anal canal or
20 rectum of a patient, which apparatus comprises an elongate flexible element designed to be introduced via the anus into the rectum and having associated therewith angular deflection detecting means for detecting angular deflection thereof.
- 25 7. Apparatus according to Claim 6, wherein said angular deflection detecting means comprises an elongate flexible core element and sensor means responsive to longitudinal

strain along opposed sides of the core element to determine angular deflection between spaced regions thereof.

8. Apparatus according to Claim 7, wherein the sensor means comprise respective elongate strain gauges extending
5 along substantially the whole length of the elongate flexible core element at radially spaced locations.

9. Apparatus according to any of Claims 6 to 8, wherein said elongate flexible element comprises a rubber or rubber-like outer sheath within which is disposed said angular
10 deflection detecting means.

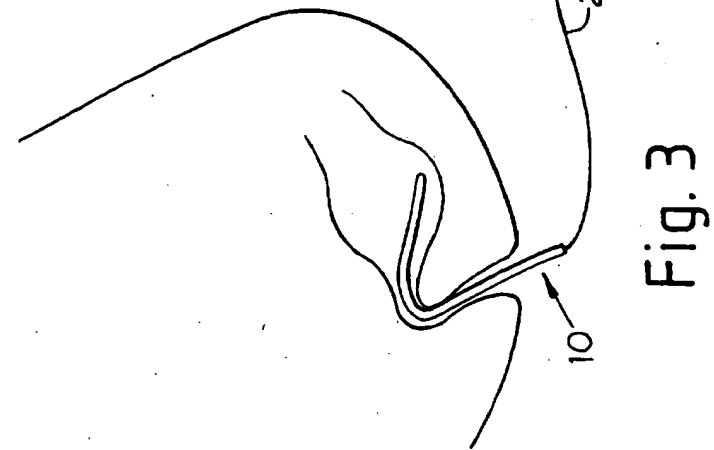
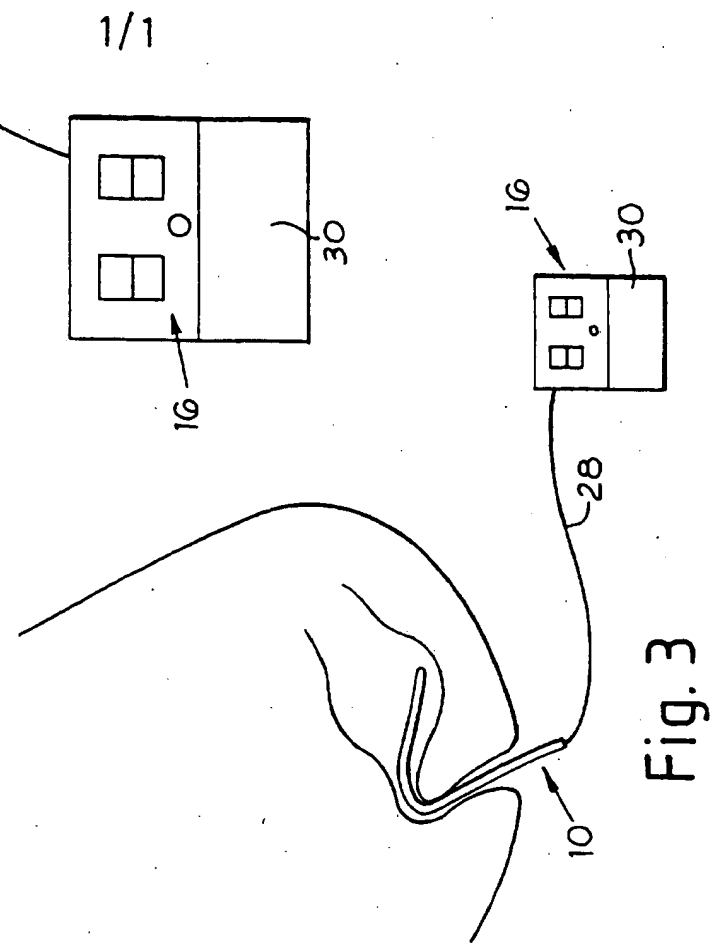
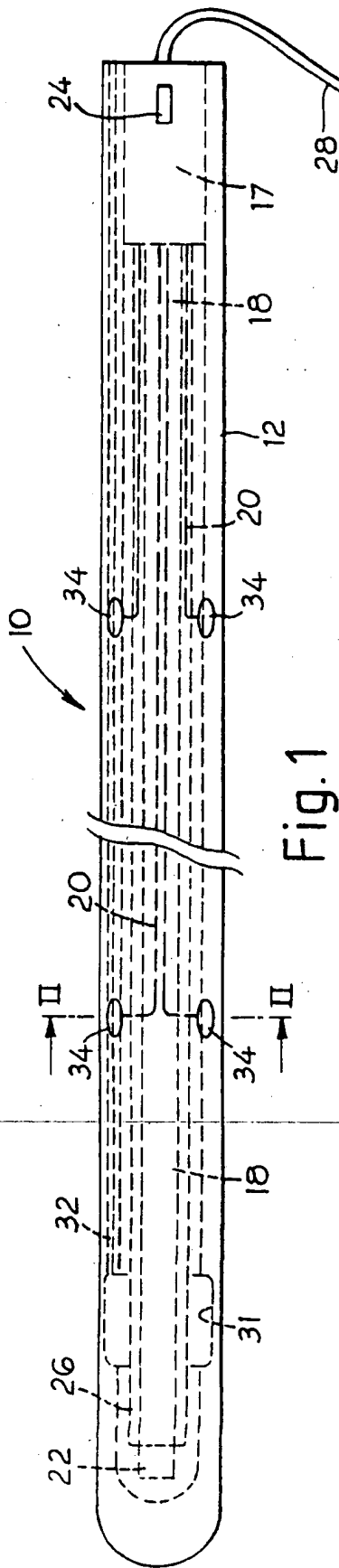
10. Apparatus according to any of Claims 6 to 9, wherein said outer sheath includes an inflatable region in the distal position thereof, and whereby said region may be inflated in use to stimulate the rectum.

11. Apparatus according to any of Claims 6 to 10, wherein said apparatus includes pressure detecting means for determining in use the pressure acting in the rectum or adjacent the anus.

12. Apparatus according to Claim 11, wherein the pressure
20 detecting means comprises one or more pressure sensors located in the outer sheath or pressure ports disposed in

the outer sheath leading to one or more associated sensors.

13. A bio-feedback sensor for training a patient with a defacatory disorder, including an elongate flexible element
25 designed to be introduced via the anus into the rectum and having associated therewith angular deflection detecting means for detecting angular deflection thereof.



INTERNATIONAL SEARCH REPORT

International Application No

PCT/GB 96/02296

A. CLASSIFICATION OF SUBJECT MATTER
 IPC 6 A61B5/03 A63B23/20

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61B A63B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US,A,4 687 002 (C.J.LAHR) 18 August 1987 see column 3, line 61 - column 6, line 57; tables 1-6	1,6
A	--- US,A,4 873 990 (H.K.HOLMES ET AL) 17 October 1989 see column 4, line 58 - column 5, line 26 see column 4, line 15 - line 23; tables 1-5	1,8
A	--- US,A,4 366 810 (C.A.SLANETZ,JR) 4 January 1983 see column 6, line 64 - column 8, line 15; tables 5-7 -----	5,11,12

☐

Further documents are listed in the continuation of box C.

☒

Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- *&* document member of the same patent family

Date of the actual completion of the international search

2 December 1996

Date of mailing of the international search report

21. 01. 97

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
 NL - 2280 HV Rijswijk
 Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl,
 Fax (+ 31-70) 340-3016

Authorized officer

Weihs, J

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inter nal Application No

PCT/GB 96/02296

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A-4687002	18-08-87	US-A- 4739767 US-A- 5005586	26-04-88 09-04-91
US-A-4873990	17-10-89	NONE	
US-A-4366810	04-01-83	US-A- 4469091	04-09-84

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ **BLACK BORDERS**
- ☐ **IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- ☐ **FADED TEXT OR DRAWING**
- ☐ **BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- ☐ **SKEWED/SLANTED IMAGES**
- ☐ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- ☐ **GRAY SCALE DOCUMENTS**
- ☐ **LINES OR MARKS ON ORIGINAL DOCUMENT**
- ☐ **REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- ☐ **OTHER:** _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.